

**Evaluation of the Region 8  
Drinking Water Laboratory Certification Program**

**by the**

**Office of Ground Water and Drinking Water  
Standards and Risk Management Division  
Technical Support Center**

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**U. S. ENVIRONMENTAL PROTECTION AGENCY**

**Cincinnati, Ohio 45268**

## **Office of Ground Water and Drinking Water Evaluation of the Region 8 Drinking Water Laboratory Certification Program**

### **INTRODUCTION**

The “Manual for the Certification of Laboratories Analyzing Drinking Water” (MCLADW, or “the Manual”) requires the Office of Ground Water and Drinking Water (OGWDW) to “review the Regional Drinking Water Laboratory Certification Programs annually and evaluate the resources and personnel available in each region to carry out the Certification Program.” Paper reviews in the form of questionnaires are done annually with on-site reviews typically conducted triennially. The triennial on-site evaluation is conducted to assess the adherence of the EPA Regional Certification Authority to the terms of the Manual, Chapters 1 – 3, Fifth Edition, EPA 815-R-05-004, 2005

Jennifer Best, Judy Brisbin, and Glynda Smith of OGWDW’s Technical Support Center (TSC) performed an on-site Quality System Analysis (QSA) of the Region 8 Drinking Water (DW) Laboratory Certification Program (LCP) on April 29 - 30, 2010, at EPA Region 8 offices located at 1595 Wynkoop Street, Denver, CO 80202-1129. An entrance briefing was held on April 29, 2010. In addition to the TSC evaluation team, the following Region 8 staff members were in attendance at the entrance briefing: Mark Burkhardt, John Gillis, Mary Goldade, Jim Gindelberger, Paula Smith, William Batschelet, Linda Himmelbauer, Jack Rycheky, Jeff Pritt, Tom Brooks, and Lee Hanley.

This on-site QSA included a review of the files for the audits of the Principal State Laboratories (PSLs) in Region 8 along with a review of the files for the audits of the laboratories in Wyoming and Tribes in Region 8. Additionally, the review included discussions regarding the Region 8 program with Linda Himmelbauer, director of the Region 8 Quality Assurance (QA) Office, who is currently also serving as the Region 8 Laboratory Certification Program Manager (LCPM) and Region 8 Certification Authority.

The Region 8 laboratory certification program is unique in that the state of Wyoming has not been delegated primacy for any National Primary Drinking Water Regulations (NPDWRs) and therefore responsibility for implementation of a laboratory certification program in WY lies with Region 8. Thus, Region 8 is responsible for ensuring that all laboratories analyzing drinking water compliance samples for public water systems in WY are certified. Region 8 accomplishes this through reciprocity with other state laboratory certification programs, along with the direct certification of several commercial laboratories. Due to the direct implementation of laboratory certification in WY and the large number of tribal laboratories for which Region 8 also has certification responsibility, the Region 8 drinking water laboratory certification program is larger in scope than any other of the USEPA regional programs.

In addition to the implementation of a laboratory certification program in WY, the Region 8 laboratory certification program also has a role, as do all other EPA Regions, in the hierarchical oversight of the state laboratory certification programs. In addition, Region 8 serves as the Certification Authority (CA) for the Principle State Laboratories (PSLs) and tribal laboratories. The oversight of the state laboratories and programs and the direct implementation (WY and

tribal) laboratory certification program overlap for many critical elements. The comments in this report generally apply, therefore, to both aspects of the Region 8 program, except as noted.

## OBSERVATIONS

### Quality and Timeliness of Laboratory Audits (including State PSLs, tribal laboratories, and WY laboratories)

#### Timeliness

The table below lists the most recent dates for on-site laboratory audits and drinking water laboratory certification program reviews in Region 8.

State PSL/ Laboratory Name	Date of last PSL Audit Chemistry	Date of last PSL Audit Microbiology	Date of last PSL Audit Radiochemistry	Date of last Laboratory Certification Program Review
CO	03/08	04/08	07/08	03/05
MT	04/10	04/10	NA	pre-2005
ND	01/10	01/10	NA	pre-2005
SD	08/07	08/07	11/08	08/04
UT	11/07 TNI AB; PSL is certified by R8	11/07 TNI AB; PSL is certified by R8	11/07	04/08 – TNI
WY Dept. Agriculture	06/04	06/04	N/A	N/A
WY Public Health Laboratory	N/A	08/09	N/A	N/A
Energy Laboratory Casper, WY	TNI	02/06	07/08	N/A
Energy Laboratory Gillette, WY	N/A	10/04	N/A	N/A
Intermountain Laboratory Gillette, WY	N/A	09/07	N/A	N/A
Intermountain Laboratory Sheridan, WY	09/07	09/07	07/08	N/A
Lander Valley Medical	N/A	08/09	N/A	N/A
Lincoln Water Quality Laboratory	N/A	08/09	N/A	N/A
National Park Service –	N/A	08/09	N/A	N/A

Mammoth				
Oglala Lakota College	N/A	08/04	N/A	N/A
Precision Analysis Pinedale, WY	N/A	02/10	N/A	N/A
Precision Analysis Riverton, WY	NO <sub>3</sub> only 04/08	09/07	N/A	N/A
Sweetwater County	N/A	08/09	N/A	N/A
Teton County Co-Op	N/A	08/09	N/A	N/A

On-site audits for drinking water laboratory certification are to be conducted on a 3-year basis as per the Manual. Region 8 utilizes Certification Officers (COs) from their laboratory to conduct the laboratory audits, including Michael Bade, Jesse Kiernan, Mark Murphy, Vince Marti and Jeff McPherson.

During recent years, the Region 8 laboratory certification program has undergone significant personnel transitions, including the loss of two microbiology COs, and the LCPM (Mr. Jim Gindelberger); the latter position has not been filled. With these changes, the Region 8 laboratory certification program has fallen significantly behind on conducting the triennial on-site audits of some of the laboratories it is responsible for certifying.

In late 2009, with the assistance of two microbiology COs from Region 6, Region 8 was able to complete several overdue laboratory audits. However, at the time of this QSA, there were still four laboratories that have not had an on-site audit in six years (shown in red in above table).

When unable to complete the on-site audits of the laboratories in a timely manner, Region 8 has issued letters extending the certification of the laboratories. As a result, some laboratories had their certification extended for up to six years, during which time there was no on-site audit. The practice of extending certification, while appropriate in limited situations (involving extenuating circumstances) had been used routinely in Region 8. As a result, for the laboratories that have not received on-site audits within the recommended time frame, there is a greater potential that the laboratories may not be producing accurate, reliable data.

Additionally, it is unclear as to how Region 8 is prioritizing the on-site audits. The Region 8 LCPM should maintain a master list of the laboratories to be audited by Region 8 and should work with the COs to arrange a schedule for the audits to be done. Currently, the list of laboratories to be audited is maintained at the Region 8 laboratory. Since there is no LCMP to coordinate the schedule of audits being performed, there is no policy/procedure in place for how the priority of laboratories to be audited is determined. It appears as if some laboratories (typically the larger PSLs) have had two on-site evaluations in the same time period that smaller laboratories serving WY and the tribal nations have not had an on-site audit. At a minimum,

Region 8 needs to develop, implement, and document a system by which to prioritize a backlog of laboratory audits.

### Quality

Region 8 is to be commended for maintaining a very qualified staff of chemistry COs. Region 8 has one of the most qualified such groups in the nation. As a result the reports prepared by these COs are very well done, reflecting very good, technical evaluations with detailed, well-written reports.

Jeff McPherson, a new Region 8 microbiology CO, is to be commended for his well prepared laboratory reports. It was evident from the review of the reports, that although Mr. McPherson has been a CO for only a short period of time, he is conducting thorough laboratory audits, as well as preparing well written reports.

While the Region 8 has a highly qualified staff of COs, due to the current backlog of laboratory audits to be performed, it is likely that Region 8 will need to use “third party *auditors*” to help complete the necessary audits. While TSC has encouraged the use of the third party auditors to help Region 8 get caught up on these audits, TSC has done so with the understanding that Region 8 is still the CA and as such, should have a presence during the laboratory audits in order to address any concerns/questions that a laboratory may have regarding the audit/evaluation process. The third party auditors, while required to have successfully completed the CO training, differ from COs in that they do not have any authority – the certification decisions will still lie with the Region 8 laboratory certification program staff. The Manual states the following regarding the use of Third Party *Auditors* (Chapter III, Section 4.2 and in Appendix C (page C-3)):

#### Chapter III, Section 4.2:

##### **4.2 Third Party Auditors**

Certification programs may employ third party auditors who meet all of the qualifications listed above. .... Although these third parties may be used to assist EPA or State certification officers, they have no authority for certification decisions and they may not make final certification decisions. These decisions rest with the EPA or the State.

#### Appendix C, p. C-3:

**Third Party Auditor:** Person or persons, not affiliated with a Region or State, who is designated by the Region or State to audit a laboratory. This person must pass the certification training course prior to auditing any laboratory unless he or she is a part of an audit team which includes a Regional/State certification officer. The third party auditor must also meet the educational/experience requirements specified in this manual. The certification decision remains with the Region.

Additionally, while most of the PSL Radiochemistry laboratories are reviewed by a “third party *expert*” under contract to TSC, it is important that the Region participate in these audits. The Manual states the following regarding the use of Third Party Experts (Appendix C, p. C-3):

**Third Party Expert:** Any person not designated as a certification officer or auditor, who is requested by the Region to assist in the audit of a laboratory because of his or her expertise in a particular area (e.g. asbestos). This person is not required to take the certification officers’ course if he or she is part of an audit team which includes a certification officer.

## **Oversight of State Certification Programs**

Annually TSC sends a questionnaire to all of the Regional LCPMs regarding the status of the certification programs within their region. EPA Regional offices typically forward this questionnaire to the states in their region to serve as an annual program review. While the questionnaire can serve as annual program reviews for the states in Region 8, more thorough evaluations of the state certification programs should occur on a triennial basis. With one exception (UT), Region 8 is not conducting reviews of the state drinking water laboratory certification programs. This deficiency was also noted in the last (2007) OGWDW program evaluation report. UT, which is a National Environmental Laboratory Accreditation Program (NELAP) Accrediting Body (AB), has had the laboratory certification program reviewed as a part of the NELAP program. Mr. Gindelberger participated in the NELAP program review of UT in 2008.

The on-site review of the state laboratory certification program is important as it serves to demonstrate that the states are properly implementing the program. Since a certified laboratory is on the front line of public health protection, a properly managed certification program serves to protect public health by ensuring that the certified laboratories are competent and producing data of known quality.

## **Direct Implementation of WY Laboratory Certification Program**

### PSL Capacity

Since Region 8 has the responsibility for direct implementation for the WY certification program, Region 8 should document its approach to ensuring PSL capability for WY. This could be done in part through utilizing the Region 8 laboratory as the WY PSL for some contaminants. Recognizing that the Region 8 laboratory does not have the capacity to analyze for all regulated contaminants, Region 8 may also elect to utilize a “network” of laboratories to ensure PSL capability for WY for the full range of regulated contaminants, and documenting agreements with those supporting laboratories.

### Tracking Certified Laboratories

One of the main reasons that the Safe Drinking Water Act specifies that certified laboratories be used for the analysis of compliance monitoring samples is for the purpose of accountability. The water systems must use a laboratory that has been certified by the State, such that the data that is generated will be of a known quality. Region 8 is responsible for ensuring that all laboratories analyzing compliance samples in WY are certified.

Currently, Region 8 directly certifies several laboratories to analyze drinking water samples. Additionally, Region 8 has reciprocity with other state certification programs, allowing laboratories certified by other states to analyze samples from WY. Region 8 posts a list on the EPA website of all laboratories certified by Region 8, both directly or through reciprocity in order to help water systems choose an appropriate laboratory. However, it has been Region 8 policy that a water system can use **any** certified laboratory, and that a laboratory does not have to be certified by Region 8 for a WY water system to use that laboratory. While this policy serves to make it easier for the WY water systems to get analyses performed, there does not seem to be

a tracking system in place to ensure that laboratories used by the WY public water systems are indeed certified.

In order to ensure that WY water systems are having their water samples appropriately analyzed, Region 8 should institute a clearer policy regarding reciprocity (perhaps requiring Region 8 certification for WY water systems) and ideally, issue a certificate to the laboratories recognized through reciprocity such that it will be easier for the WY water systems to understand which laboratories they may utilize for compliance sample analyses.

### **Laboratory Audit and Certification Program Files**

The files for all laboratories certified by Region 8 and all laboratory certification programs under the oversight of Region 8 were reviewed during this on-site evaluation. It was evident that Mr. Gindelberger kept the files in good order during his tenure, with all files containing audit reports, communication with/about the laboratories, certificates and certification extension letters. It was likewise evident that since Mr. Gindelberger's departure, the files have not been kept up to date or complete. There were some more limited documents associated with laboratories audited during 2009; however the files as a whole are incomplete.

These incomplete files have contributed to an error that has been made regarding the certification status of at least one laboratory, which has created greater potential for situations where laboratories may not be producing accurate, reliable data. Case in point is the WY Department of Agriculture Laboratory. This laboratory's file contains documents showing that the laboratory underwent a successful audit in 2004, and although the laboratory was due to have been audited again in 2007, the laboratory's certification was extended by Region 8 in both 2007 and 2008. The file contains no PT results received by Region 8 for this laboratory for this time period (conversation with Region 8 personnel confirmed that no PT results were received during this period). Thus, it is likely that this laboratory's certification should have expired in 2007, or possibly revoked prior to 2007 for a failure to document successful analysis of PTs.

There is a note in the file from Ms. Mary Goldade documenting some important information she uncovered during a recent file review, none of which had been previously documented in the file. Ms. Goldade's findings (per conversations with Mike Bade, CO from the Region 8 laboratory), explain that in the 2005 timeframe, the laboratory had significant staff and management turnover. Region 8 was told in 2007, 2008, and 2009 that the laboratory "was not prepared" for an audit to take place.

The WY Dept. of Agriculture laboratory's certification should have expired in 2007 (or have been revoked sooner if PTs were not being completed), but was extended through 2009. However, at the time of this review, the laboratory was still analyzing drinking water compliance samples, approximately 500 per year. This laboratory has not adequately demonstrated its ability to properly analyze drinking water samples and has had no recent oversight by Region 8.

The fact that this laboratory, producing results of unknown quality, is still analyzing drinking water samples reflects inadequate attention on the part of the Region 8 laboratory certification program.

It is critical that all significant communication that occurs between any Region 8 personnel (whether CO or LCP staff) and laboratories, along with notification of any significant changes (personnel/equipment, etc.) that occur at any of the laboratories certified by Region 8, be documented in the laboratory's file. Region 8's failure to do so has resulted in a laboratory maintaining a certified laboratory status without ongoing oversight by the Region.

Successful participation in a Proficiency Test (PT) study is required annually under the NPDWRs. Region 8 is currently not tracking the PT results for any of the certified laboratories, and as a result, for some of the laboratories certified by Region 8, there are no PT results available for the past several years. Since laboratory certification depends on successfully completing PTs, it is imperative that Region 8 establish a system to track PT results for all certified laboratories.

Additionally, the Region 8 laboratory certification program needs to begin tracking follow up to on-site laboratory audits. From a review of the files, it was difficult to ascertain whether or not laboratories had responded to/completed any of the corrective actions recommended by the COs in the on-site evaluation reports.

### **Communications with State Counterparts**

Meetings between the Regions and States are described in the Manual (Chapter 2, page 1) to provide a forum for dissemination of information and to foster partnerships amongst the states and regional laboratory certification personnel. Historically, Region 8 held annual meetings with the states with TSC participating during the triennial on-site program reviews. However, these meetings have not been held in recent years. In October 2009, Ms. Himmelbauer facilitated a meeting with all of the states in Region 8, with remote participation by TSC. To enhance the relationship and the communication between the Region 8 laboratory certification program and the states it oversees, TSC would encourage Region 8 to continue to hold these meetings, and to consider more frequent meetings via teleconference.

### **Resources**

#### **Staffing**

In our view, the Region 8 laboratory certification program is currently critically understaffed. At present, Ms. Himmelbauer serves in the role of director of the QA Office while also serving as the Region 8 CA and LCPM. We believe that this is more than one person can reasonably be expected to do.

The EPA OARM 1200 Delegations Manual, Chapter 9 (SDWA), 9-3 Certification of Laboratories and Responsible State Officials states that the CA authority "may be redelegated to the Division Director level." Since it does not address further redelegation, and since Ms. Himmelbauer's position is not at the Division Director level, Region 8 should identify an individual at the appropriate level to serve as the Region 8 CA.

The Region 8 laboratory certification program previously had only one full-time staff member, Mr. Gindelberger (the COs comprise the rest of the limited FTE allotted to the Laboratory Certification Program), and as was noted in the 2007 OGWDW program review, the laboratory

certification program was deemed understaffed by TSC's evaluation team. As a result of the understaffing, Region 8 was unable to consistently perform audits on a routine schedule. Upon the departure of Mr. Gindelberger, there were no full-time staff members devoted to the laboratory certification program, leaving very limited CO involvement with the Region 8 LCP. Ms. Himmelbauer has done an exemplary job towards getting the program back on track; however, TSC does not believe that she has adequate resources to fully implement such a large program. TSC believes that Region 8 needs to invest more resources into this critical program to strengthen it and to ensure public health is protected.

The role of the laboratory certification program is a mixture of enforcement and education. A strong technical assistance component of a laboratory certification program allows the laboratories to gain knowledge and understanding of the regulations and standards.

While it is evident that Region 8 has the expertise to provide technical support to the laboratory certification program (especially for chemistry), the availability of that support to the states and the certified laboratories has been limited. Whereas the majority of the regions do provide a significant amount of such support, there is very little documentation in the files indicating that this is the case in Region 8.

Region 6 microbiology COs conducted on-site evaluations of several laboratories in WY in August 2009. From the audit reports and conversations with the Region 6 COs, it is clear that the COs identified some serious concerns regarding the quality of the work being performed by the laboratories and that those laboratories would benefit from Region 8 technical support. Several of these laboratories were dropped to provisional certification until they could demonstrate that they had implemented recommended changes; they sought help from the Region 6 COs in some cases to implement suggested changes.

Additionally, while conducting this QSA, the TSC audit team was asked to provide some technical support to a WY laboratory wishing to become certified because there were no laboratory staff members available to assist. In other regions, the laboratory certification program is at the laboratory and this type of arrangement seems to be more conducive to technical support being provided to the laboratories and states in the region. Since the Region 8 laboratory certification program is physically separated from the laboratory, it may be more challenging for the two programs to collaborate. Such collaboration, however, will serve to strengthen both programs.

In our experience, technical support from the region to the laboratories also enhances the respect for the regional certification process/program by the laboratories, and the responsiveness of those laboratories. As an example of the need for this, there were two laboratories that still had not responded to the findings of the audit report nine months after the report was issued (and repeated attempts by the CO to obtain the data). Additionally, the supervisor at one of the laboratories asked the CO questions that reflected a poor understanding of promulgated method requirements. Region 8 is encouraged to build stronger technical support back into the laboratory certification program, as it will serve to strengthen the drinking water program in Region 8 and better protect public health.

## Travel

Region 8 travel resource currently appears to be adequate. Importantly, we note that in 2009 and in 2010, Region 8 was able to fund travel for auditors from other regions to assist in the backlog of on-site audits.

## **COMMENDATIONS:**

1. Linda Himmelbauer, director of the Region 8 QA Office, deserves much credit for her work towards rebuilding the Region 8 laboratory certification program. Since her appointment to the QA Office, Ms. Himmelbauer has done an exemplary job educating herself about the drinking water laboratory certification program, and identifying deficiencies. Ms. Himmelbauer was very responsive to the OGWDW evaluation team, and very frank about areas where improvement is needed.
2. The Region 8 QA Office conducted an internal review of their own laboratory certification program files, a process performed by Mary Goldade. Ms. Goldade's notes were excellent, allowing her to examine the various components of the laboratory certification program and assess deficiencies. As Region 8 rebuilds the laboratory certification program, internal reviews of this type will be quite helpful.

## **FINDINGS:**

1. **For consistency with the Manual, four laboratories are in critical need of on-site audits.** Some of these laboratories have not had an on-site audit since 2004, making them three years delinquent. These laboratories are currently analyzing drinking water compliance samples with inadequate oversight. This represents a potential risk to public health and deserves immediate attention.
2. **To ensure compliance with primacy conditions, Region 8 needs to increase its oversight of the state laboratory certification programs within its purview.** Per the Manual, Region 8 should be reviewing the certification programs annually with triennial onsite evaluations.
3. **For consistency with the Manual, Region 8, as the certification authority, needs to increase its participation in audits performed by third party experts or third party auditors.** In the case of the use of the third party *expert*, the CO should be present on-site during the audit. When third party *auditors* are used, this participation could be accomplished via a teleconference for the entrance meeting and exit debriefs.
4. **To ensure compliance with regulatory requirements, Region 8 needs to review and track PT results and other information related to a laboratory's certification status.** Successful completion of PTs on an annual basis is required under federal regulations in order for a laboratory to maintain a certified status.
5. **To ensure compliance with primacy conditions, Region 8 needs to document the availability of laboratory capacity for all regulated contaminants for WY.**

**6. To ensure compliance with regulatory requirements, Region 8 needs to establish a system to ensure that all water systems in WY use a certified laboratory for compliance sample analysis**

**7. Per the Agency's Delegation Manual, Region 8 needs to establish an individual at the Division Director-level to serve as the Region 8 Certification Authority.**

## **RECOMMENDATIONS**

1. TSC recommends that Region 8 fill the LCPM position and the additional vacancies/needs in the laboratory certification program. TSC is confident that many of the issues identified will benefit from addressing these staffing needs. In our experience, it is not practical for 1.3 FTE to effectively run a program of this size.

2. TSC recommends additional clerical support to properly organize the certified laboratory files. Ideally, for each state within Region 8 there would be the following files: Chemistry PSL documents (audit reports, technical communication, certificates, etc.), Microbiology PSL documents (same documents as previous), and Radiochemistry PSL documents (same as previous). Additionally, there should be a file containing all of the documentation for the state laboratory certification program oversight/reviews. Hardcopies of PTs should be included in these files.

3. TSC recommends that only copies of the last two on-site audit reports for each laboratory on file, as well as the corresponding PT results. Older documents should be archived in records storage. Per the Manual (Chapter 3):

“records for on-site laboratory assessments and certification program reviews be maintained in an easily accessible central location for a period of 6 years to include the last two onsite audits, or longer if required by specific State regulations. This includes records/correspondence used to determine compliance with the requirements in this manual. Records may include checklists, corrective action reports, final reports, certificates, PT study results and related documents”

4. TSC recommends that Region 8 develop and implement a policy or SOP that details how Region 8 will prioritize and schedule onsite laboratory audits. This policy or SOP should include language that details under what circumstances a laboratory's certification status will be extended.

5. TSC recommends that Region 8 develop and implement a system for tracking information regarding each laboratory. Currently, information regarding each laboratory may reside with the CO that audited the laboratory. While this information should be placed in a file for the purpose of records, it would also be helpful if there were a spreadsheet with some type of tracking for each of the laboratories. Region 8 has oversight over many laboratories, and it is impractical for the details to be maintained with so many individuals. Additionally, this spreadsheet could serve to help ensure that the laboratory has appropriately responded to the findings and corrective actions from the audits.

6. TSC recommends that Region 8 provide more technical support to both the laboratories certified by Region 8 and the QA Office, which oversees the LC program. Providing technical support to the states and laboratories will help to build more credibility for the Region 8 laboratory certification program. In addition, it will serve to ensure the small laboratories are running the analyses appropriately, thus serving to further protect public health.

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